Remarks

The Amendments

Claims 39 and 41 have been amended to delete the language "shown in". This is not a narrowing amendment. The amendment merely clarifies the transitional phrases used in the claims. Claims 39 and 41 have also been amended to remove the variant language; however, applications reserve the right to prosecute claims containing these variants in a continuation application.

Rejection of Claims 39-42 Under 35 U.S.C. §102(a)

Claims 39-42 stand rejected under 35 U.S.C. §102(a) as allegedly anticipated by Waner *et al.* Applicants respectfully traverse the rejection.

Under 35 U.S.C. § 102, a claim is anticipated only if each and every element as set forth in the claim is found in a single art reference. *Verdegaal Bros. v. Union Oil Co.*, 2 USPQ2d 1051, 10533 (Fed. Cir. 1987); *In re Recombinant DNA Technology Patent and Contract Litigation*, 30 USPQ2d 1881, 1885 (S.D. Ind.1993) ("A patent is anticipated only if all the elements and limitations of the claims are found within a single, prior art reference."); *Structural Rubber Products Co. v. Park Rubber Co.*, 223 USPQ 1264, 1270 (Fed. Cir. 1984) (All elements of the claimed invention must be contained in a single prior art disclosure and must be arranged in the prior art disclosure as in the claimed invention); M.P.E.P § 2131. Furthermore, no difference may exist between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of invention. *In re Recombinant DNA Technology Patent and Contract Litigation*, 30 USPQ2d 1881, 1885 (S.D. Ind.1993). Also, the identical invention must be described or

McDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001
FACSIMILE (312) 913-0002

shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); *Chester v. Miller*, 15 USPQ2d 1333 (Fed. Cir. 1990); M.P.E.P. § 2131.

The Office Action asserts that there is nothing on record to show that the claimed device differs from the device of Waner. The Office Action asserts that Waner teaches the use of a device comprising *Ehrlichia* antigen and that the applicant has provided no side-by-side comparison to show that the claimed polypeptides differ from the Waner polypeptides. However, Waner does not teach or suggest an element of the claims, that is, SEQ ID NOs:3-7. Therefore, Waner cannot anticipate the claims. The Office Action appears to assert, however, that a teaching of SEQ ID NOs:3-7 is inherently present in Waner.

The fact that a certain characteristic may occur or be present in a prior art reference is not sufficient to establish the inherency of that characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted); MPEP §2112.01. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support

McDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001
FACSIMILE (312) 913-0002

the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); MPEP §2112.01.

The Office has not provided a basis in fact and/or technical reasoning to show that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Waner does not teach or suggest the use of polypeptide fragments in the detection of *Ehrlichia.* Nor has that Office Action alleged that the mixture of protein antigens or whole cell antigens taught by Waner would be fragmented in any way.

Additionally, the claimed device provides greater sensitivity and specificity than the reagents used in Waner (*i.e.,* DH82 cells that are heavily infected with *E. canis* and *E. canis* antigen derived from mouse J774.A1-infected cells). See attached declaration of Dr. Chandrashekar, paragraphs 2-4 and 6. Therefore, the claimed devices differ from those of Waner because they provide greater sensitivity and specificity than those described in Waner.

Finally, it should be noted that Waner does not teach or suggest the use of any types of *E. chaffeensis* polypeptides in a device. SEQ ID NOs:3-7 of the present invention are *E. chaffeensis* derived polypeptides and therefore cannot be anticipated by Waner.

Waner does not anticipate claims 39-42 because Waner does not teach, suggest, or inherently disclose each and every element of claims 39-42. Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 39-42 Under 35 U.S.C. §102(b)

McDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001
FACSIMILE (312) 913-0002

Claims 39-42 stand rejected under 35 U.S.C. §102(a) as allegedly anticipated by Cadman *et al.* Applicants respectfully traverse the rejection.

The Office Action asserts that there is nothing on record to show that the claimed device differs from the device of Cadman. The Office Action asserts that Cadman teaches the use of a device comprising *Ehrlichia* antigen and that the applicant has provided no side-by-side comparison to show that the claimed polypeptides differ from the Cadman polypeptides. However, Cadman does not teach or suggest an element of the claims, that is, SEQ ID NOs:3-7. Therefore, the Cadman reference cannot anticipate the claims. The Office Action appears to assert, however, that a teaching of SEQ ID NOs:3-7 is inherently present in Cadman.

The Office has not provided a basis in fact and/or technical reasoning to show that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Cadman does not teach or suggest the use of polypeptide fragments in the detection of *Ehrlichia*. Nor has that Office Action alleged that the mixture of protein antigens or whole cell antigens in Cadman would be fragmented in any way.

Additionally, the claimed device provides greater sensitivity and specificity than the reagents used in Cadman (*i.e.*, DH82 cells which are heavily infected with *E. canis* and *E. canis* antigens purified from infected DH82 cells). See attached declaration of Dr. Chandrashekar, paragraphs 2-3 and 5-6. Therefore, the claimed devices differ from those of Cadman because they provide greater sensitivity and specificity than those described in Cadman.

McDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001
FACSIMILE (312) 913-0002

It should be noted that Cadman does not teach or suggest the use of any types of *E. chaffeensis* polypeptides in a device. SEQ ID NOs:3-7 of the present invention are *E. chaffeensis* derived polypeptides and therefore cannot be anticipated by Cadman.

Cadman does not anticipate claims 39-42 because Cadman does not teach, suggest, or inherently disclose each and every element of claims 39-42. Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 21 and 39-42 Under 35 U.S.C. §112, second paragraph

Claims 21, and 39-42 stand rejected under 35 U.S.C. §112, second paragraph as allegedly lacking definiteness. Applicants respectfully traverse the rejection.

The Office Action asserts that claims 39-42 are indefinite for the use of the term "a polypeptide shown in SEQ ID NOs:3-7." Claims 39-42 have been amended to remove the "shown in" language.

The Office Action asserts that claims 39-42, in particular claim 41, are indefinite because it is unclear if a product or process is being claimed. Claim 41 clearly recites that "the instructions for use indicate" a certain process. Thus, one of skill in the art would understand that claim 41 is further describing the instructions for use of the claimed device. The claim is therefore definite and applicants respectfully request withdrawal of the rejection.

The Office Action asserts that claims 39-42, in particular claim 41, are indefinite for the use of the term "under conditions." Claim 41 recites that certain polypeptides that specifically bind to an anti-*Ehrlichia* antibody, are contacted with a test sample suspected of comprising antibodies to *Ehrlichia*, under conditions that allow polypeptide/antibody

McDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001
FACSIMILE (312) 913-0002

complexes to form. The claim is describing an extremely well known method of detecting the presence of antibodies to a bacterial pathogen comprising the detection of polypeptide/antibody complexes. One of skill in the art, given the specification, which includes working examples of such detection, would clearly understand the meaning of "under conditions" that allow polypeptide/antibody complexes to form because one of skill in the art would be very familiar with such methods. The claims are therefore definite and applicants respectfully request withdrawal of the rejection.

The Office Action asserts that claim 21 is indefinite because it recites "amino acid substitution variants." The test for definiteness is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). One of skill in the art would understand the meaning of amino acid substitution variants given the specification. The specification teaches amino acid substitution variants and how to identify such variants at, *inter alia*, page 7, line 14 through page 9, line 7. Additionally, this claim language was addressed and approved in the Examiner interview of telephonic interview of July 10, 2003.

Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 21-24 Under 35 U.S.C. §102(b)

Claims 21-24 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Rikihisa *et al.* Applicants respectfully traverse the rejection.

The Office Action asserts that Rikihisa teaches devices that contain *Ehrlichia* polypeptides for sero-diagnosing ehrlichiosis in mammals. The Office Action teaches

McDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001
FACSIMILE (312) 913-0002

that Rikihisa teaches an amino acid variant of SEQ ID NO:7 and anticipates the claimed invention. Rikihisa does not teach or suggest an element of the claims, that is, polypeptides consisting of SEQ ID NOs:1-7. Therefore, the Rikihisa reference cannot anticipate the claims. The Office Action appears to assert, however, that a teaching of SEQ ID NOs:1-7 is inherently present in Rikihisa.

The Office has not provided a basis in fact and/or technical reasoning to show that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Rikihisa does not teach or suggest the use of polypeptide fragments in devices and in particular does not teach or suggest the particular fragments shown in SEQ ID NOs:1-7. Nor has that Office Action alleged that the whole recombinant protein antigens in Rikihisa would be fragmented in any way.

Additionally, the claimed devices provide greater sensitivity than the reagents taught in Rikihisa (*i.e.,* whole, recombinant proteins). See attached declaration of Dr. Chandrashekar, paragraphs 2-3 and 6-7. Therefore, the claimed devices differ from those of Rikihisa because they provide greater sensitivity than those described in Rikihisa.

Rikihisa does not anticipate claims 21-24 because Rikihisa does not teach, suggest, or inherently disclose each and every element of claims 21-24. Applicants respectfully request withdrawal of the rejection.

Request for Reconsideration of Finality of the Office Action

Applicants respectfully request reconsideration of finality of the Office Action issued on November 17, 2003. The rejection of claims 21-24 under 35 U.S.C. §102(b) as allegedly anticipated by Rikihisa *et al.* was not necessitated by amendment of the claims.

McDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001
FACSIMILE (312) 913-0002

Claims 21-24 have always recited the polypeptides shown in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7 and one or more types of variants of those sequences. Rikihisa is cited as teaching an amino acid variant of SEQ ID NO:7. Since the amendments did not change the fact that SEQ ID NO:7 or variants thereof were being claimed, the amendments of the previous response did not necessitate the rejection of claims 21-24 over this newly cited reference. Applicants respectfully request withdrawal of the finality of the Office Action.

Applicants respectfully request the withdrawal of all rejections and the speedy allowance of the claims.

Respectfully submitted,

Date: 2/17/04 By: _____

Lisa M.W. Hillman
Reg. No. 43,673

McDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001
FACSIMILE (312) 913-0002